DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District 94319d

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

October 9, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Frank N. Konyn
Partner
Frank Konyn Dairy
2165 Oro Verde Road
Escondido, CA 92027

W/L 02-04

Dear Mr. Konyn:

Our records reflect you are one of the partners of Frank Konyn Dairy located at 15777 Old Milky Way, Escondido, CA. An investigation of your dairy operation conducted by our investigator on June 4, 2003, confirmed that you offered animals for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (henceforth the "Act"), and caused a new animal drug to become adulterated within the meaning of section 501(a)(5).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. A food is further adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions . . . whereby it may have been rendered injurious to health." In this case, "insanitary conditions" means that you hold animals, which are ultimately offered for sale for slaughter as food, under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues may enter the food supply.

A new animal drug is adulterated under section 501(a)(5) of the Act if it is administered in a manner other than in accordance with the directions specified in the labeling, thereby making it unsafe within the meaning of section 512(a)(1)(B).

On or about March 17, 2003, you sold a culled dairy cow identified by USDA Laboratory report 443797 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the liver at 0.13 parts per million (ppm) and in the kidney at 0.79 ppm. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle.

Our investigation also found that you hold animals under improper conditions whereby diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for the appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are considered adulterated under the Act.

In addition, our investigator found that you use injectable penicillin, such as Agripharm's Pen-Aqueous, on dairy cattle in a manner contrary to the approved labeling. Injectable penicillin is labeled for intramuscular use at 1 cc per hundred pounds of body weight. Your use of this drug at a dose of 20 cc's is not in agreement with the approved labeling. Fifteen (15) cc's would be the approved dose for a 1,500 pound cow.

For your information, in October 1994, Congress passed the Animal Medicinal Drug Use Clarification Act, which permits extra-label use of drugs under certain controlled conditions as specified in 21 Code of Federal Regulations (CFR) Part 530. "Extra-label use" means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. Extra-label use is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship and in conformance with criteria set forth in the regulation.

The above is not intended to be an all-inclusive list of violations. As a producer of animals, which are offered for use as food, you are responsible for assuring that your overall operations and the food you distribute are in compliance with the law.

Please note that it is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse which ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should take prompt action to correct the above violations and to assure that the procedures you have established will prevent their recurrence. Failure to do so may result in regulatory action, such as injunction, without further notice. This letter constitutes official notification under the law and provides you an opportunity to correct.

Please advise this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step that has been taken to correct the violations and prevent their recurrence. If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which such corrections will be made. If you have any questions or need clarifications regarding this letter prior to your written response, you may contact Barbara Rincon, Compliance Officer at telephone number (949) 608-4439.

Your written response should be directed to:

Dannie Rowland
Acting Director, Compliance Branch
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2445

Sincerely,

Alonza E. Cruse
District Director